June 10, 2003 – 0845

Received call in response to public notice in Denver Daily News.

Questions asked:

Q: What is this Product?
A: Described

Q: Is it considered a drug?
A: Yes

Q: Is it better / safer than – will it be used instead of blood?
A: Performs one function of the blood (carries O_2). Although blood supply is safe, it may carry less risk of viral transmission secondary to screening and production process (described)

Q: How will it be used in study?
A: Described randomization and procedures.

Q: Who makes product?
A: Northfield Laboratories.

Q: When are meetings?
A: Gave info for this week – she asked for specifics for Wednesday night (6/11 Den Health Foundation)

Encouraged this caller to review website and call again if she has further questions.

June 13, 2003

Received call in response to public notice.

Questions asked:

Q: When will the study start?

A: There's really no way of knowing for sure, it depends response from the community and on the IRB. We hope within the next 30-60 days.

Q: Are you (we) confident in the product?

A: Yes. In the patients we've give the product to in previous trials, we showed that it not only does what it's supposed to (delivers oxygen) but we've not seen any serious adverse effects attributable to the study product.

Q: Do you (we) anticipate other sites starting soon?

A: I don't know where the other sites are in the process.

Q: Has Northfield (sponsor) been helpful in the process?

A: Yes

The caller closed the conversation by saying that he "hopes things go well."

Assessment: Positive

JL

EEW

Long, Jeff

From: Long, Jeff
Sent: Wednesday, June 18, 2003 1:41 PM
To: 'Hicks, Chris'
Subject: RE: Trials

Hi Chris,

One person who has been to two meetings is opposed to the trial, at least at this time, apparently on the basis of the waiver of informed consent only. Overall, the community response has been overwhelmingly positive.

Feel free to contact me again at any time.

Jeff

Jeffrey S. Long, R.R.T.
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Jeff.Long@dhha.org

-----Original Message-----
From: Hicks, Chris [SMTP:chrishicks@Ferrellgas.com]
Sent: Wednesday, June 18, 2003 11:40 AM
To: Long, Jeff
Subject: Trials

Dr. Long,

I discussed the Polyheme trial with you last week. I had one additional question I was hoping you could answer. Has the trial faced opposition in any of the meetings held thus far?

Thanks for your help.

Chris Hicks.

Long, Jeff

From: Long, Jeff
Sent: Friday, June 13, 2003 9:29 AM
To: Kobayashi, Joyce, S
Subject: RE: consent waiver

Hi Joyce,

I'd be happy to meet with you. My schedule is pretty full right now so let me know what would be best for you.

I should point out that the IRB has not approved the *exception from informed consent requirements* yet, though they have approved the trial design.. The waiver comes after the community consultation process, if the IRB feels we've informed the community adequately and if the response from the community is not negative. You are welcome to come to our meetings, of which there are only two remaining:

Tuesday, June 24, 9:00 a.m.
Denver City Council
Human Services, Health and Environment Committee
Denver City and County Building, Room 450

Tuesday, June 24, 7:00 p.m.
Denver Health Community Open Forum
Rita Bass Trauma and EMS Education Institute
190 West 6th Avenue (South-East Corner of 6th and Bannock)

I can't make our application available to you, but would be happy to discuss the process. Additionally I'd recommend a few websites to review:

http://www.denverhealth.org/TraumaCenter/Polyheme.aspx

http://www.northfieldlabs.com

http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?FR=50.24

http://comirbweb.uchsc.edu/

Feel free to call or respond at your convince.

Best regards,

Jeff

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-----Original Message-----

From: Kobayashi, Joyce, S
Sent: Friday, June 13, 2003 8:19 AM
To: Long, Jeff
Cc: Moore, Ernest, M.D.
Subject: consent waiver

I am a psychiatrist and have written several book chapters about informed consent; Dr. Moore has indicated that it would be
alright if I asked you more details about the community education process so that I could write something about the consent waiver that the uchsc has approved for your study: may I meet with you or talk with you on the phone? Would it
be feasible to attend one of your community meetings? May I review the IRB approval application re: the consent process?
Thanks very much for your help and all the best for this landmark study. JSK

Long, Jeff

From: Long, Jeff
Sent: Friday, June 13, 2003 9:18 AM
To: 'Earthlink'
Subject: RE: PolyHeme

Hi Mr. Stamatis,

We have extensive experience using PolyHeme, but not other blood substitutes.

Please feel free to contact if you have further questions or would like any additional information. Also, you can visit our website http://www.denverhealth.org/TraumaCenter/Polyheme.aspx You've likely already seen Northfield's site, but if not - www.northfieldlabs.com.

Best regards,

Jeff

-----Original Message-----
From: Earthlink [SMTP:hstamatis@sprynet.com]
Sent: Friday, June 13, 2003 8:54 AM
To: Long, Jeff
Subject: PolyHeme

Dear Mr. Long,

As a small stockholder in Northfield Labs, I am looking forward to the results of this study most anxiously. If it all possible can you tell me if your facility is involved in any other similar studies being conducted involving blood substitutes other than Northfield's PolyHeme?

Best regards,
Harry Stamatis

Long, Jeff

From: Rosario C. de Baca [rcdebaca@larasa.org]
Sent: Thursday, June 12, 2003 4:14 PM
To: Long, Jeff
Subject: RE: PolyHeme

Dear Dr. Long:

Thank you very much. I've read the abstract & this is interesting due to the religious & sicle cell anemia. Your outreach to explain this study to the community is wonderful. I hope all goes smoothly with the IRB.

Rosario Ortiz C. de Baca, Program Coordinator
Center for Community and Behavioral Health
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Denver, CO 80223
rcdebaca@larasa.org

ph (303) 722-5150, x109
fax (303 722-5118

-----Original Message-----
From: Long, Jeff [mailto:Jeff.Long@dhha.org]
Sent: Thursday, June 12, 2003 2:21 PM
To: Rosario CdeBaca
Subject: PolyHeme

Roesario,

This is the abstract for the article I told you about. I'll make a photocopy of the entire article and mail it to you.

Best regards,

Jeff
<<Entrez-PubMed.htm>>
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